

EXHIBIT K

From: Taylor Lodise <Taylor_Lodise@njd.uscourts.gov>
Sent: Tuesday, June 11, 2024 9:49 AM
To: Wyatt, Geoffrey M (WAS); Brown, Allison M (NYC); Klein, Bradley A (WAS); Hazlett, Abigail A.; Joshi, Rupal (WIL); Pete Marketos; 'Josh Russ'; Andrew Wirmani; Whitney Wendel
Cc: Argjenta Kaba; Kimberly Stillman
Subject: [Ext] 12-cv-7758 - Final Jury Instructions
Attachments: 12-7758 - Tab 6 v.8 - Final Jury Instructions - Clean.pdf

Dear Counsel,

Please see attached the final instructions that will be read to the jury.

Best,
Taylor

Taylor Lodise
Law Clerk to the Honorable Zahid N. Quraishi, U.S.D.J.
District of New Jersey
Phone: 609.989.2105
Judge Quraishi's Preferences: <https://www.njd.uscourts.gov/content/zahid-n-quraishi>

UNITED STATES OF AMERICA,
et al., ex rel. JESSICA PENELOW
and CHRISTINE BRANCACCIO,

Plaintiffs, :

v. :

JANSSEN PRODUCTS, LP, :

Defendant.

:
:
:
: Case No. 12-7758 (ZNQ)(JBD)
:
:
:
:
:
:
:
:
:
:

FINAL JURY INSTRUCTIONS

TABLE OF CONTENTS

	<u>Page</u>
INSTRUCTION NO. 1 – Introduction; Role of Jury	3
INSTRUCTION NO. 2 – Summary of Case	4
INSTRUCTION NO. 3 – Conduct of Jury	6
INSTRUCTION NO. 4 – Bench Conferences	8
INSTRUCTION NO. 5 – Evidence	9
INSTRUCTION NO. 6 – Direct and Circumstantial Evidence	11
INSTRUCTION NO. 7 – Credibility of Witnesses	12
INSTRUCTION NO. 8 – Preponderance of The Evidence	13
INSTRUCTION NO. 9 – Use of Deposition	14
INSTRUCTION NO. 10 – Use of Interrogatories	15
INSTRUCTION NO. 11 – Use of Requests for Admission	16
INSTRUCTION NO. 12 – Charts and Summaries in Evidence	17
INSTRUCTION NO. 13 – Charts and Summaries Not Admitted in Evidence	18
INSTRUCTION NO. 14 – Opinion Testimony	19
INSTRUCTION NO. 15 – Transcript of Audio-Recorded Conversation	20
INSTRUCTION NO. 16 – Corporate Responsibility	21
INSTRUCTION NO. 17 – Overview of Relators’ Claims	22
INSTRUCTION NO. 18 – Anti-Kickback Claims	23
INSTRUCTION NO. 18.1 – Anti-Kickback Claims – Elements – Remuneration	24
INSTRUCTION NO. 18.2 – Anti-Kickback Claims – Elements – Inducement	25
INSTRUCTION NO. 18.3 – Anti-Kickback Claims – Elements – Federal Health Care Program	26

INSTRUCTION NO. 18.4 – Anti-Kickback Claims – Elements – Knowledge and Willfulness	27
INSTRUCTION NO. 18.5 – Anti-Kickback Claims – Elements – Knowledge.....	28
INSTRUCTION NO. 18.6 – Anti-Kickback Claims – Elements – Willfulness.....	29
INSTRUCTION NO. 19 – False Claims Act – Elements.....	30
INSTRUCTION NO. 19.1 – False Claims Act – Elements – Falsity.....	31
INSTRUCTION NO. 19.2 – False Claims Act – Elements – Causation.....	32
INSTRUCTION NO. 19.3 – False Claims Act – Elements – Knowledge	33
INSTRUCTION NO. 19.4 – False Claims Act – Elements – Materiality	34
INSTRUCTION NO. 20 – Corporate Integrity Agreements and Settlement Agreement	35
INSTRUCTION NO. 21 – Withheld Documents	37
INSTRUCTION NO. 22 – FDA Approval	38
INSTRUCTION NO. 23 – State Law Claims.....	39
INSTRUCTION NO. 24 – Texas False Claims Act.....	41
INSTRUCTION NO. 25 – Damages – Overview	42
INSTRUCTION NO. 26 – Damages – Measure of Damages	43
INSTRUCTION NO. 27 – Damages – Parties That Recover.....	44
INSTRUCTION NO. 28 – Number of False Claims.....	45

INSTRUCTION NO. 1 – Introduction; Role of Jury

Now that all the evidence has been presented, I will instruct you on the law and then the attorneys will present to you closing arguments to summarize and interpret the evidence in a way that is helpful to their clients' positions. As with opening statements, closing arguments are not evidence. After that you will retire to the jury room to deliberate on your verdict in this case. You will decide what the facts are and then apply those facts to the law that I will give to you.

You and only you will be the judges of the facts. You will have to decide what happened. I play no part in judging the facts. You should not take anything I might have said or did during the trial, or anything else I may say or do, as indicating what I think of the evidence or what your verdict should be. My role is to be the judge of the law. I make whatever legal decisions have to be made during the course of the trial, and I will explain to you the legal principles that must guide you in your decisions. You must follow that law whether you agree with it or not.

INSTRUCTION NO. 2 – Summary of Case

This case is brought under a federal law called the False Claims Act. Additionally, this case is brought under similar laws in twenty-six states and the District of Columbia, each of which have their own version of the False Claims Act. Individuals who bring a lawsuit on behalf of the government under a False Claims Act are called “Relators.” In order for a private citizen to bring claims under the False Claims Act, the private citizen must disclose his or her allegations to the Department of Justice. The private citizen, known as the Relator, may then pursue his or her claims in federal court. The Department of Justice is not involved in this case for the purposes of this trial.

In this lawsuit, Relators Jessica Penelow and Christine Brancaccio claim Defendant Janssen Products, LP (“Janssen”) violated federal and state False Claims Acts by knowingly causing materially false claims for reimbursement of two HIV medicines, Prezista and Intelence, to be submitted to three government programs: Medicare, Medicaid, and the AIDS Drug Assistance Program (referred to as “ADAP”). Relators allege that, from 2006 to 2014, Janssen engaged in off-label marketing and kickback schemes related to Prezista and Intelence.

With regard to off-label marketing, Relators allege Janssen unlawfully marketed (1) Prezista as being “lipid neutral,” “lipid friendly,” or as having a similar impact on lipids as a competitor drug, Reyataz, which Relators claim was false; (2) Prezista as being suitable for treatment-naïve patients before the FDA approved it for treatment-naïve patients; (3) Intelence as being suitable for once-a-day dosing when it was only approved for twice-a-day dosing; and (4) Intelence as being suitable for treatment-naïve patients when it was only approved for treatment-experienced patients. Relators allege that these uses were contrary to the drugs’ FDA-approved labels and/or not medically necessary and reasonable.

Regarding kickbacks, Relators allege that Janssen paid prescribers to serve on a Speaker Program and paid for prescribers' travel, meals, and hotel stays in order to induce them to prescribe its drugs Prezista and Intelence, and/or to reward them for doing so.

Janssen denies these allegations. Janssen states that the claims submitted to the government for reimbursement of Prezista and Intelence were appropriate, its sales representatives properly promoted Prezista and Intelence to doctors, and that it properly used speaker programs to educate doctors about Prezista, Intelence, and HIV-related issues. Janssen further states its actions did not influence physicians to improperly prescribe Prezista and Intelence and were not material to the government's reimbursement of these medicines.

INSTRUCTION NO. 3 – Conduct of Jury

Now, a few words about your conduct as jurors.

First, I again instruct you that during the trial and until you have heard all of the evidence and have retired to the jury room to deliberate, you are not to discuss the case with anyone, not even among yourselves. If anyone should try to talk to you about the case, including a fellow juror, bring it to my attention promptly. There are good reasons for this ban on discussions, the most important being the need for you to keep an open mind throughout the presentation of evidence. I know that many of you use cell phones, smart phones, and other portable electronic devices; laptops, netbooks, and other computers both portable and fixed; and other tools of technology, to access the internet and to communicate with others. You also must not talk to anyone about this case or use these tools to communicate electronically with anyone about the case. This includes your family and friends. You may not communicate orally with anyone about the case on your cell phone, smart phone, or portable or fixed computer or device of any kind; or use these devices to communicate electronically by messages or postings of any kind including e-mail, instant messages, text messages, text or instant messaging services such as Twitter, or through any blog, website, internet chat room, or by way of any other social networking websites or services including Facebook, LinkedIn, and YouTube.

If any lawyer, party, or witness does not speak to you when you pass in the hall, ride the elevator, or the like, remember it is because they are not supposed to talk or visit with you, either. That is why you are asked to wear your juror tags. It shows that you are someone who is not to be approached in any way.

Second, do not read or listen to anything related to this case that is not admitted into evidence. By that I mean, if there is a newspaper article or radio or television report relating to this case, do not read the article or watch or listen to the report. In addition, do not try to do any independent research or investigation on your own on matters relating to the case or this type of case. Do not do any research on the internet, for example. You are to decide the case upon the evidence presented at trial. In other words, you should not consult dictionaries or reference materials, search the internet, websites, blogs, or use any other electronic tools to obtain information about this case or to help you decide the case. Please do not try to find out information from any source outside the confines of this courtroom.

Again, do not reach any conclusion on the claims or defenses until all of the evidence is in. Keep an open mind until you start your deliberations at the end of the case.

INSTRUCTION NO. 4 – Bench Conferences

During the trial it was necessary for me to talk with the lawyers out of your hearing by having bench conferences.

We are not trying to keep important information from you. Those conferences were necessary for me to fulfill my responsibility, which is to be sure that evidence is presented to you correctly under the law.

I may not have granted an attorney's request for a conference. Do not consider my granting or denying a request for a conference as any indication of my opinion of the case or of what your verdict should be.

INSTRUCTION NO. 5 – Evidence

The evidence from which you are to find the facts consists of the following:

1. The testimony of the witnesses; and
2. Documents and other things received as exhibits.

The following things are not evidence:

1. Statements, arguments, and questions of the lawyers for the parties in this case;
2. Objections by lawyers;
3. Any testimony I tell you to disregard; and
4. Anything you may see or hear about this case outside the courtroom.

You must make your decision based only on the evidence that you see and hear in court.

Do not let rumors, suspicions, or anything else that you may see or hear outside of court influence your decision in any way.

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

There are rules that control what can be received into evidence. When a lawyer asked a question or offered an exhibit into evidence, and a lawyer on the other side thought that it was not permitted by the rules of evidence, that lawyer may have objected. This simply means that the lawyer requested that I make a decision on a particular rule of evidence. You should not be influenced by the fact that an objection was made. Objections to questions are not evidence.

Lawyers have an obligation to their clients to make objections when they believe that evidence being offered is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it. If the objection was sustained, ignore the question. If it was overruled, treat the answer like any other. If you were instructed that some item of evidence is received for a limited purpose only, you must follow that instruction.

Also, certain testimony or other evidence was ordered struck from the record and you were instructed to disregard that evidence. Do not consider any testimony or other evidence that got struck or excluded. Do not speculate about what a witness might have said or what an exhibit might have shown.

INSTRUCTION NO. 6 – Direct and Circumstantial Evidence

There are two types of evidence that you may use in reaching your verdict. One type of evidence is called “direct evidence.” An example of “direct evidence” is when a witness testifies about something that the witness knows through his own senses—something the witness has seen, felt, touched, or heard or did. If a witness testified that he saw it raining outside, and you believed him, that would be direct evidence that it was raining. Another form of direct evidence is an exhibit where the fact to be proved is its existence or current condition.

The other type of evidence is called circumstantial evidence. “Circumstantial evidence” is proof of one or more facts from which you could find another fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

You should consider both types of evidence that are presented to you. The law makes no distinction in the weight to be given to either direct or circumstantial evidence. You are to decide how much weight to give any evidence.

INSTRUCTION NO. 7 – Credibility of Witnesses

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You are the sole judges of the credibility of the witnesses. “Credibility” means whether a witness is worthy of belief. You may believe everything a witness says, or only part of it, or none of it. In deciding what to believe, you may consider a number of factors, including the following:

1. The opportunity and ability of the witness to see or hear or know the things the witness testifies to;
2. The quality of the witness’s understanding and memory;
3. The witness’s manner while testifying;
4. Whether the witness has an interest in the outcome of the case or any motive, bias, or prejudice;
5. Whether the witness is contradicted by anything the witness said or wrote before trial or by other evidence;
6. How reasonable the witness’s testimony is when considered in the light of other evidence that you believe; and
7. Any other factors that bear on believability.

The weight of the evidence to prove a fact does not necessarily depend on the number of witnesses who testify. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves.

INSTRUCTION NO. 8 – Preponderance of The Evidence

This is a civil case. Relators are the parties who brought this lawsuit. Janssen is the party against which the lawsuit was filed. Relators have the burden of proving their case by what is called the preponderance of the evidence. That means Relators have to prove to you, in light of all the evidence, that what they claim is more likely so than not so. To say it differently: If you were to put the evidence favorable to Relators and the evidence favorable to Janssen on opposite sides of the scales, Relators would have to make the scales tip somewhat on their side. If Relators fail to meet this burden, the verdict must be for Janssen. If you find after considering all of the evidence that a claim or fact is more likely so than not so, then the claim or fact has been proved by a preponderance of the evidence.

In determining whether any fact has been proved by a preponderance of evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

You may have heard of the term “proof beyond a reasonable doubt.” That is a stricter standard of proof, and it applies only to criminal cases. It does not apply in civil cases such as this. So you should put it out of your mind.

INSTRUCTION NO. 9 – Use of Deposition

A deposition is the sworn testimony of a witness taken before trial. The witness is placed under oath and swears to tell the truth, and lawyers for each party may ask questions. A court reporter is present and records the questions and answers.

INSTRUCTION NO. 10 – Use of Interrogatories

You may have heard answers that a party gave in response to written questions submitted by the other side. The written questions are called “interrogatories.” The written answers were given in writing and under oath, before the trial.

INSTRUCTION NO. 11 – Use of Requests for Admission

Evidence was presented to you in the form of admissions to the truth of certain facts. These admissions were given in writing before the trial, in response to requests that were submitted under established court procedures. You must treat these facts as having been proved.

INSTRUCTION NO. 12 – Charts and Summaries in Evidence

The parties have presented exhibits in the form of charts and summaries. I decided to admit these charts and summaries in place of the underlying documents that they represent in order to save time and avoid unnecessary inconvenience. You should consider these charts and summaries as you would any other evidence.

INSTRUCTION NO. 13 – Charts and Summaries Not Admitted in Evidence

Certain charts and summaries that have not been received in evidence have been shown to you in order to help explain or illustrate the contents of books, records, documents, testimony, or other evidence in the case. For example, you may see charts and summaries during the parties' opening and closing statements or during the testimony of opinion witnesses. Unless the charts or summaries were specifically admitted as trial exhibits, they are not themselves proof of any facts. They are not binding on you in any way. If they do not correctly reflect the facts shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the evidence.

INSTRUCTION NO. 14 – Opinion Testimony

You will hear testimony containing opinions from expert witnesses. In weighing this opinion testimony, you may consider their qualifications, the reasons for their opinions, and the reliability of the information supporting those opinions, as well as the factors I have previously mentioned for weighing the testimony of any other witness. The opinions of the expert witnesses should receive whatever weight and credit, if any, you think appropriate, given all the other evidence in the case.

In deciding whether to accept or rely upon the opinions of the expert witnesses, you may consider any bias that they may have, including any bias that may arise from evidence that they have been or will be paid for reviewing the case and testifying or from evidence that the expert witnesses testify regularly and make a large portion of their income from testifying in court.

INSTRUCTION NO. 15 – Transcript of Audio-Recorded Conversation

You have heard conversations that were recorded. This is proper evidence for you to consider. You have seen transcripts of some recordings to help you identify speakers and as a guide to help you listen to the recordings. If you believe at any point that the transcript said something different from what you heard on the recording, remember it is the recording that is the evidence, not the transcript. If at any time there was a variation between the recording and the transcript, you must be guided solely by what you heard on the recording and not by what you saw in the transcript.

INSTRUCTION NO. 16 – Corporate Responsibility

The defendant Janssen is a corporation. A corporation is a legal entity that may act only through individuals who are called its agents. The agents of a corporation are its officers, directors, employees, and other persons who are authorized by the corporation to act for it.

You must give to a corporate defendant the same impartial consideration of the evidence that you would give to any individual.

The legal responsibility of a corporation, if any, is based on the conduct of its agents. To find Janssen liable under the False Claims Act, you will need to find that the Relators proved by a preponderance of the evidence that the elements of each claim are satisfied through the acts or omissions of officers, directors, employees, or other agents of Janssen; that such agents performed such acts within the course and scope of his or her employment; and that such acts or omissions were intended for the benefit of the corporation.

INSTRUCTION NO. 17 – Overview of Relators' Claims

In this case, Relators seek recovery from Janssen under the federal and state False Claims Acts. Relators allege that Janssen is liable under the False Claims Acts due to its alleged off-label marketing. Relators also allege that Janssen is liable under the False Claims Acts due to alleged violations of the Anti-Kickback Statute.

Relators allege that Janssen caused the submission of false claims in multiple, independent ways.

First, a claim is false if it is ineligible for reimbursement under a federal health care program. In determining whether a claim is eligible for reimbursement, you must consider that federal health care programs, including Medicare Part D, Medicaid, and ADAP, will cover and pay for a drug that is used for a “medically accepted indication,” which means any FDA-approved use on the label that is supported by one or more citations in certain drug compendia. Coverage for drugs may also be excluded if they are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Second, a claim is also false if Janssen violated the Anti-Kickback Statute in connection with the claim.

I will now explain to you the elements of the Anti-Kickback Statute.

INSTRUCTION NO. 18 – Anti-Kickback Claims

I instruct you that any claim submitted to a federal health care program resulting from a violation of the Anti-Kickback Statute is a false claim under the False Claims Act. Therefore, for the kickback claims, in determining whether Janssen violated the False Claims Act, you will first have to determine whether Janssen violated the Anti-Kickback Statute.

For you to find that Janssen violated the Anti-Kickback Statute, Relators must prove each of the following elements by a preponderance of the evidence.

First, that Janssen offered or paid any remuneration, including any kickback or bribe directly or indirectly, openly or secretly, in cash or in kind;

Second, that one purpose of the remuneration offered or paid was to induce or reward prescriptions of Prezista or Intelence;

Third, that claims for payment for those prescriptions were submitted to a federal health care program, and that there was some evidence in this case of a link between the alleged inducement and the claims submitted for reimbursement; and

Fourth, that Janssen acted knowingly and willfully.

I will now provide you with further explanation of each of these elements.

INSTRUCTION NO. 18.1 – Anti-Kickback Claims – Elements – Remuneration

The first element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that Janssen offered or paid remuneration. “Remuneration” means the transfer of anything of value from one person or entity to another person or entity. Remuneration can be direct or indirect, overt or covert, in cash or can include anything of value in any form whatsoever.

INSTRUCTION NO. 18.2 – Anti-Kickback Claims – Elements – Inducement

The second element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that one of the purposes of the remuneration was to induce or reward the referral, purchase, order, recommendation of any item or service paid for by a federal health care program. It is not a defense that there might have been some other reason for the remuneration if you find by a preponderance of the evidence that one of the purposes of the remuneration was to induce or reward the referral, purchase, order, recommendation of any item or service to be paid for by the federal health care program. Unlawful inducement does not need to be the primary purpose of the remuneration.

INSTRUCTION NO. 18.3 – Anti-Kickback Claims – Elements – Federal Health Care Program

The third element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that claims for payment for those prescriptions were submitted to a federal health care program, and that there was some evidence in this case of a link between the alleged inducement and the claims submitted for reimbursement. The term “federal health care program” means any plan or program that provides health benefits and is funded entirely or indirectly by the United States government. I instruct you that Medicare, Medicaid, and ADAP are “federal health care programs.”

INSTRUCTION NO. 18.4 – Anti-Kickback Claims – Elements – Knowledge and Willfulness

The fourth element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that Janssen acted knowingly and willfully.

INSTRUCTION NO. 18.5 – Anti-Kickback Claims – Elements – Knowledge

An act is done “knowingly” for purposes of the Anti-Kickback Statute if the act is done voluntarily and intentionally, and not because of a mistake or accident.

INSTRUCTION NO. 18.6 – Anti-Kickback Claims – Elements – Willfulness

The term “willfully” means acting with a purpose to disobey or disregard the law. An act is done “willfully” if Janssen knew that the act was unjustifiable or wrong, even if Janssen was not aware of the specific law or rule that they may have been violating. Relators do not have to prove that Janssen specifically intended to violate the Anti-Kickback Statute.

INSTRUCTION NO. 19 – False Claims Act – Elements

As explained earlier, Relators allege that Janssen is liable under the federal False Claims Act stemming from its alleged off-label marketing, and stemming from its alleged violations of the Anti-Kickback Statute. Therefore, the next thing that you will have to consider is whether Janssen is liable under the False Claims Act.

For you to find that Janssen is liable under the federal False Claims Act, Relators must prove the following elements by a preponderance of the evidence: (1) falsity; (2) causation; (3) scienter, which means culpable state of mind; and (4) materiality.

I will now explain each of these elements in turn.

INSTRUCTION NO. 19.1 – False Claims Act – Elements – Falsity

First, Relators must prove by a preponderance of the evidence that the claims submitted or caused to be submitted by Janssen were false. I have instructed you that a claim resulting from a violation of the Anti-Kickback Statute is false. I have also instructed you that a claim made to a federal health care program is false if it seeks reimbursement for a prescription that is not eligible for reimbursement.

INSTRUCTION NO. 19.2 – False Claims Act – Elements – Causation

Second, Relators must prove by a preponderance of the evidence that Janssen caused the claims to be submitted to the government. Janssen's conduct may be found to have caused the submission of a claim for Medicare, Medicaid, or ADAP reimbursement if (1) the conduct was a substantial factor in inducing providers to submit claims for reimbursement, and (2) the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of Janssen's conduct.

INSTRUCTION NO. 19.3 – False Claims Act – Elements – Knowledge

Third, Relators must prove by a preponderance of the evidence that Janssen acted knowingly. “Knowingly” means that Janssen had actual knowledge, acted with deliberate ignorance to the truth or falsity of their statements, or recklessly disregarded the truth or falsity of the information. Relators are not required to show proof of specific intent to defraud.

INSTRUCTION NO. 19.4 – False Claims Act – Elements – Materiality

Fourth, Relators must prove by a preponderance of the evidence that Janssen’s alleged Anti-Kickback Statute or off-label marketing violations were material to the Government’s payment decision. “Material” means that it had a natural tendency to influence, or was capable of influencing, the payment or receipt of money or property.

INSTRUCTION NO. 20 – Corporate Integrity Agreements and Settlement Agreement

You have heard testimony that Janssen was subject to two Corporate Integrity Agreements, in 2010 and 2013, as well as Settlement Agreements in 2010 and 2013, with the federal government. The Corporate Integrity Agreements and Settlement Agreements were related to the resolution of allegations brought by the government concerning alleged off-label marketing of different products and alleged kickbacks paid through speaker programs related to different products. These different products did not include Prezista and Intelence.

This evidence of the Corporate Integrity Agreements and Settlement Agreements was admitted only for limited purposes. You may consider this evidence only for the purpose of deciding whether:

- Janssen acted knowingly or willfully regarding the conduct alleged by Relators;
- Janssen had the motive or opportunity to engage in the conduct alleged by Relators;
- Janssen acted with a method of operation as evidenced by a unique pattern regarding the conduct alleged by Relators;
- Janssen's conduct was not a mistake, an accident, or an impossibility;
- Janssen's conduct was not made in good faith; and
- the government would deem the conduct alleged in this case to be material in deciding whether to reimburse claims for Prezista and Intelence.

You may also consider whether the existence and terms of the Corporate Integrity Agreements and Settlement Agreements contradict the testimony of a witness in assessing the credibility of that witness.

Do not consider this evidence for any other purpose.

Of course, it is for you to determine whether you believe this evidence and, if you do believe it, whether you accept it for the purpose offered. You may give it such weight as you feel it deserves, but only for the limited purposes that I described to you.

There are no claims at issue in this lawsuit regarding the alleged other acts that resulted in the Corporate Integrity Agreements or Settlement Agreements. You may not consider the Corporate Integrity Agreements or the Settlement Agreements as a substitute for proof that Janssen engaged in the conduct alleged in this case. Specifically, you may not use this evidence to conclude that because there were allegations of off-label marketing and kickbacks paid through speaker programs with respect to other products, Janssen must have engaged in the conduct alleged in this case.

INSTRUCTION NO. 21 – Withheld Documents

During the course of this trial, it was discovered that Janssen withheld documents that were responsive to Relators’ discovery requests and which Janssen was obligated to turn over well in advance of the trial. Specifically, Janssen withheld documents pertaining to allegations of another Janssen employee, Joanne Cesario, concerning Janssen’s off-label promotion of Prezista and Intelence. You are permitted, but not required, to infer that Janssen withheld this evidence because it was unfavorable to Janssen.

INSTRUCTION NO. 22 – FDA Approval

You have heard testimony from a Janssen employee, Dr. Amit Patel, about the FDA's silence in response to certain of Janssen's promotional advertising submissions regarding Prezista and lipids. You also heard him testify that Janssen considered the FDA's silence in response to those advertising submissions as the FDA's indirect or tacit approval of Janssen's advertising.

I am instructing you that there is no statute or regulation that says that the FDA's silence means that it has approved a promotional advertising submission.

INSTRUCTION NO. 23 – State Law Claims

In addition to the federal False Claims Act, Relators also assert claims on behalf of the States of New Jersey, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia under their versions of the False Claims Act. These State False Claims Acts allow Relators like Ms. Penelow and Ms. Brancaccio to bring a lawsuit on behalf of a state government.

Earlier, I gave you instructions about the law applicable to the federal False Claims Act and Anti-Kickback Statute. Those instructions apply to the States' claims as well. Each of the States operates a Medicaid program with state and federal funds. As a result, the Anti-Kickback Statute is one of the laws that is applicable to these Medicaid programs.

Most States' False Claims Acts are modeled on the federal False Claims Act and have very similar or identical provisions. These State False Claims Acts impose liability on a defendant that knowingly presents, or causes to be presented, a false or fraudulent claim for payment. Therefore, if after following my earlier instructions, you found that Janssen violated the federal False Claims Act, you must also find that Janssen violated the analogous provisions of all of the States' False Claims Acts, except I will provide separate instructions for Texas.

Accordingly, if you find Janssen liable under the standards explained earlier for the False Claims Act as to any Medicaid reimbursements in a particular State (other than Texas), then you should find that Janssen is also liable under that State's law. Conversely, if you find that Janssen

is not liable under the False Claims Act for any Medicaid reimbursements in a particular State, then you should find that Janssen is not liable under that State's law.

INSTRUCTION NO. 24 – Texas False Claims Act

For Texas, you should follow the instructions I gave in connection with the federal False Claims Act, except as modified by the instructions I will now give you.

Janssen is liable under the Texas False Claims Act if you find that, by a preponderance of the evidence, Relators established that Janssen knowingly violated the Texas anti-kickback law. The Texas anti-kickback law makes it illegal to offer or pay, directly or indirectly, in cash or in kind to induce a person to refer an individual to another person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program.

The term “knowingly” as used in the Texas False Claims Act means that the defendant (1) had knowledge of the information; (2) acted with conscious indifference to the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information.

INSTRUCTION NO. 25 – Damages – Overview

If you find that Janssen violated the False Claims Act or its State analogues, then you must determine damages resulting from the violation.

I will now explain the law related to damages. However, the fact that I am instructing you on the issue of damages should not be taken to mean that I have any view on whether you should find liability. If you do not find Janssen liable, then you should not assess any damages.

Relators must prove the Government's damages with reasonable certainty. You may not award damages that are speculative—that is, damages that might be possible but are based solely on guesswork. Relators are not required to prove the exact amount of damages, but Relators must show sufficient facts and circumstances to permit you to make a reasonable estimate of the damages.

INSTRUCTION NO. 26 – Damages – Measure of Damages

The measure of damages under the False Claims Act is the amount of money that the Government paid out by reason of the false claims.

If you find that Janssen submitted false claims or caused false claims to be submitted to a federal health care program during the damages period, then the full amount paid by the Government as the result of those false claims is the amount of damages.

To account for the various State analogues to the False Claims Act, you must differentiate between damages suffered by the United States, the twenty-six states, and the District of Columbia. Accordingly, the verdict form will ask you to specify the amount of damages (if any) that you attribute to the United States, the twenty-six states, and the District of Columbia.

INSTRUCTION NO. 27 – Damages – Parties That Recover

Any money recovered under the federal False Claims Act or the state analogues goes to the United States and the States. The United States and the States may then provide the Relators with a portion of that recovery. In determining the amount of the damages that the United States and the States are entitled to, you are not to consider the possibility of a Relators' share of the recovery.

INSTRUCTION NO. 28 – Number of False Claims

If you find that Janssen violated the False Claims Act, then you must also identify the number of false or fraudulent claims that were submitted to the United States, the States, and the District of Columbia.

Again, the fact that I am instructing you on the issue of the number of false claims should not be taken to mean that I have any view on whether you should find liability. If you do not find Janssen liable under the False Claims Act, then you should not assess the number of false claims.